

## CLAIMS

What is claimed:

1. A method of increasing systemic bioavailability of a hormone administered by inhalation comprising:

5 administering to the respiratory system of a patient or animal in need of said hormone aerodynamically light particles that have a mass mean diameter greater than 5  $\mu\text{m}$ , an aerodynamic diameter less than 4.7  $\mu\text{m}$  and that include said hormone,

10 wherein the particles are delivered and deposited to the patient's or animal's lungs and the hormone is released in the patient's or animal's blood stream for at least 4 hours.

2. The method of Claim 1 wherein the hormone is insulin.

- 15 3. The method of Claim 1 wherein the hormone is testosterone.

4. The method of Claim 1 wherein the particles further include a biodegradable material.

- 20 5. The method of Claim 1 wherein the mass mean diameter is greater than 10  $\mu\text{m}$ .

6. The method of Claim 1 wherein the mass mean diameter is greater than 20  $\mu\text{m}$ .

7. The method of Claim 1 wherein the hormone is released in the patient's or  
25 animal's blood stream for at least 10 hours.

8. The method of Claim 1 wherein the hormone is released in the patient's or animal's blood stream for at least 24 hours.

5 9. The method of Claim 1 wherein the hormone is released in the patient's or animal's blood stream for at least 48 hours.

10. A method of delivering a hormone to the pulmonary system to a patient or animal, comprising:

10 administering, via inhalation, particles that include a hormone and a biodegradable material, have an aerodynamic diameter less than about 4.7  $\mu\text{m}$  and a mass mean diameter greater than about 5  $\mu\text{m}$ ,

15 wherein the hormone is delivered and deposited in the patient's or animal's lungs and is released in the patient's or animal's blood stream for at least 4 hours.

11. A method of increasing the bioavailability of a hormone, comprising:

20 administering to a patient or animal, via inhalation, particles that include a hormone and a biodegradable material, have an aerodynamic diameter less than about 4.7  $\mu\text{m}$  and a mass mean diameter greater than about 5  $\mu\text{m}$ ,

25 wherein the hormone is delivered and deposited in the patient's or animal's lungs and is released in the patient's or animal's blood stream for at least 4 hours.

12. A method for making aerodynamically light particles for administration of a hormone to the respiratory tract by inhalation, the method comprising forming particles that include the hormone and a biodegradable material and that have an aerodynamic diameter that is less than 4.7  $\mu\text{m}$  and a mass mean diameter that is

greater than 5  $\mu\text{m}$ .

13. The method of Claim 12 wherein the hormone is insulin.

5 14. The method of Claim 12 wherein the hormone is testosterone.

15. The method of Claim 12 wherein the mass mean diameter is greater than 10  $\mu\text{m}$ .

16. The method of Claim 12 wherein the mass mean diameter is greater than 20  $\mu\text{m}$ .

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17. The method of Claim 12 wherein the aerodynamically light particles are made by spray-drying.

18. The method of Claim 12 wherein the aerodynamically light particles are made by solvent evaporation.

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